NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

STATE OF NEW JERSEY, Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendant.	:	Civil Action No. 07-4698 (JAP) **OPINION**

PISANO, District Judge:

Before the Court are defendant United States Department of Health and Human Services' ("DHHS") motion to dismiss this suit pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), and plaintiff State of New Jersey's motion for partial summary judgment under Federal Rule of Civil Procedure 56. New Jersey seeks relief under Title XXI of the Social Security Act, 42 U.S.C. §§ 1397aa, *et seq*., the Declaratory Judgment Act, 28 U.S.C. § 2201, and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 501, *et seq*., challenging new "policy guidelines" regarding the administration of the State Children Health Insurance Program ("SCHIP"), disseminated by DHHS in August 2007. New Jersey argues, *inter alia*, that the new "guidelines" are burdensome, mandatory rules which significantly decrease eligibility for its SCHIP plan. DHHS maintains that because the August 2007 policies constituted guidelines, and not rules, and no corrective action has been taken against New Jersey (nor is any imminent), no ripe case or controversy exists and the Court therefore lacks jurisdiction over New Jersey's

complaint. For the reasons set forth below, DHHS' motion to dismiss for lack of subject matter jurisdiction is granted. Because this Court is without jurisdiction to entertain the instant suit, New Jersey's motion for partial summary judgment is rendered moot, and the Court will not address it.

I. Background

A. The State Children's Health Insurance Program

Congress enacted the State Children's Health Insurance Program as part of the Balanced Budget Act of 1997, Pub. L. 105-33, 111 Stat. 251, under Title XXI of the Social Security Act, 42 U.S.C. §§ 1397aa, *et seq.*, to "enable [states] to initiate and expand the provision of child health assistance to uninsured low-income children in an effective and efficient manner." 42 U.S.C. § 1397aa(a). Through the provision of matching federal funds, the state programs are designed to expand health insurance coverage for uninsured children of families whose incomes are too high to qualify for insurance under Medicaid but too low to purchase private health insurance independently. *See* 42 U.S.C. § 1397jj. The federal funds are made available through capped allotments based on a formula that takes into account the number of targeted low-income children in the state. 42 U.S.C. § 1397dd(b). The SCHIP statute defines a "low-income child" as one coming from a family with an income at or below 200 percent of the federal poverty line ("FPL"). 42 U.S.C. § 1397jj(c)(4). In contrast, a "targeted low-income child" is defined as either a low-income child, or a child whose family income exceeds 200 percent of the FPL but is less than fifty (50) percentage points above the Medicaid applicable income level or who resides in a state that does not have a Medicaid applicable income level. 42 U.S.C. § 1397jj(b)(1). To date, approximately 6.6 million children are enrolled in SCHIP programs nationwide.

The SCHIP program is administered by the Centers for Medicare and Medicaid ("CMS"), an agency within DHHS that has regulatory oversight of all state SCHIP programs, activities, and expenditures. 42 C.F.R. §§ 457.40, 457.50. Although the SCHIP regulations promulgated by CMS note that, "[w]ithin broad Federal rules, each State decides eligible groups, types and ranges of services, payment levels for benefit coverage, and administrative and operating procedures," 42 C.F.R. § 457.1 (2008), the state's plan must be approved by the CMS Administrator in order to receive federal funds under the program. 42 U.S.C. § 1397aa(b). Therefore, each state's plan must set forth the state's intended use of the funds, and include information regarding: (1) the extent of children within the state that currently have health insurance; (2) current measures taken by the state "to identify and enroll all uncovered children who are eligible to participate in public health insurance programs;" (3) how the plan coordinates with such state measures to increase coverage; (4) the child health insurance coverage under the plan for "targeted low-income children;" (5) eligibility standards, including those related to income and resources; (6) outreach activities; and (7) methods employed in the plan to assure the quality and appropriateness of care and access to covered services. *See* 42 U.S.C. §§ 1397aa(b), 1397bb(a). The plans must also meet particular coverage requirements and include strategic objectives and performance goals. *See* 42 U.S.C. §1397cc.

In addition to descriptions of the eligibility standards employed by the state, the state's plan must also include procedures to screen and redetermine eligibility at least annually. 42 U.S.C. § 1397bb(b)(3). States are empowered to determine eligibility for SCHIP enrollment by setting the permissible maximum family income level; however, if the state elevates the permissible income level above 200 percent of the FPL, the state must implement certain

additional measures to ensure that public coverage under a state's plan does not substitute for, or "crowd out," private, employer-sponsored group insurance plans. 42 C.F.R. §§ 457.40, 457.805. Waiting periods for eligibility are one such example. *See* 42 C.F.R. § 457.810(a) (subject to certain exceptions, "[a]n enrollee must not have had coverage under a group health plan for a period of at least 6 months prior to enrollment in a premium assistance program. A State may not require a minimum period without coverage under a group health plan that exceeds 12 months."). However, the statute does not mandate use of any particular crowd-out procedures. In fact, CMS declined to identify specific procedures when promulgating the statute's implementing regulations, acknowledging that the state's "substitution prevention efforts should be considered in the context of the entire state plan with consideration given to a state's particular needs and goals." 66 Fed. Reg. 2604 (Jan. 11, 2001).

States must also submit to CMS annual reports detailing, *inter alia*, the state's success in reducing the amount of uncovered, low-income children, the efficacy of the state's crowd-out procedures, the state's progress in achieving other strategic objectives identified in its plan, and "successes and barriers in State plan design and implementation, and the approaches the State is considering to overcome these barriers." 42 C.F.R. § 457.750(b). As part of its review for compliance, CMS analyzes "the State's policies and procedures, on-site reviews of selected aspects of agency operation, and examination of samples of individual case records." 42 C.F.R. § 457.200(a). CMS reviews plans on a case-by-case basis "to determine whether [a plan] meets or continues to meet the requirements for approval under relevant Federal statutes, regulations, and guidelines furnished by CMS to assist in the interpretation of these regulations," and either "approves or disapproves of the plan . . . in its entirety." 42 C.F.R. §§ 457.150(a), (b), and (c).

B. Administrative and Judicial Review Procedures

Review procedures vary slightly depending on whether they are initiated by the state or the agency. If a state applies for approval of a plan amendment, once it has submitted a plan amendment to CMS, the amendment is deemed approved unless CMS notifies the state within 90 days that it is disapproved or that additional information is needed. 42 U.S.C. § 1397ff(c); 42 C.F.R. § 457.160(b). When CMS reviews a potential amendment to a state plan, it examines the amendment independently but may request further information regarding how the proposed amendment affects other, unamended, portions of the plan. 42 C.F.R. § 457.150(a). Once approved by CMS, a state's plan continues in effect until either the state amends the plan or CMS Administrator finds the plan to be in substantial noncompliance with the requirements of the SCHIP statute. 42 U.S.C. § 1397jj(e). In the event that the amendment is disapproved, the state may request reconsideration, by way of a full hearing with discovery, within 60 days. 42 U.S.C. § 1316(a)(2); 42 C.F.R. § 457.203(a). If the CMS Administrator at the end of the hearing process determines that CMS's initial disapproval of the amendment was incorrect, CMS must pay the incorrectly denied funds in a lump sum. 42 C.F.R. § 457.203(d).

The procedure differs if CMS initiates a noncompliance proceeding. The CMS Administrator may find a plan to be substantially noncompliant at any time but may impose no monetary sanctions absent written notice of the noncompliance to the state within ninety days of the plan's submission, "a reasonable opportunity for correction," and a hearing. 42 U.S.C. § 1397ff(c); 42 C.F.R. § 457.204. Upon a finding of noncompliance, CMS must notify the state in writing why its plan is noncompliant and "[i]f enforcement action is proposed, that the State has a reasonable opportunity for correction . . . before the Administrator takes final action" by

withholding federal funds. 42 C.F.R. § 457.204(d). However, "[h]earings are generally not called until a reasonable effort has been made to resolve the issues through conferences and discussions" which may continue up to the date of the hearing. 42 C.F.R. § 457.204(a)(2). In the event of an adverse hearing determination, CMS may prospectively withhold future federal funds payments, in whole or in part. 42 C.F.R. § 457.204(d).

The state may appeal to the Administrator's decision regarding either approvability of plan material or compliance with federal requirements within sixty days of the determination to the regional U.S. Court of Appeals for the circuit in which the state is located. 42 C.F.R. § 457.208. If such appeal is taken, the agency must file in the appellate court the record of the proceedings on which its determination was based. 42 C.F.R. § 457.208(b)(2). The court is bound by the agency's findings of fact if they are supported by substantial evidence in the record, but the court may, for good cause shown, remand the case to the agency to take further evidence. 42 U.S.C. § 1316(a)(4); 42 C.F.R. § 457.208(c). On remand, the Administrator may make new findings of fact and may modify his previous determination. 42 U.S.C. § 1316(a)(4); 42 C.F.R. § 457.208(d).

C. New Jersey's SCHIP Plan

New Jersey's plan, presently known as NJ FamilyCare, presently covers approximately 124,000 low-income children. (Compl. ¶¶ 3, 6, 23.) "NJ FamilyCare provides coverage to uninsured children in families that are not otherwise eligible for Medicaid with gross incomes at or below 350 percent of the FPL." (*Id.* ¶ 24.) New Jersey's original plan was approved by CMS' predecessor agency in 1998. (*Id.* ¶ 25.) The initial plan established three separate insurance plans for children based on whether their gross family income was below 133 percent (Plan A),

between 133 and 150 percent (Plan B), or between 150 and 200 percent of the FPL (Plan C). (*Id.* ¶ 25.)

New Jersey sought a plan amendment in 1999 to add a fourth separate insurance plan for children whose gross family incomes exceeded the FPL by no more than 350 percent (Plan D), allowing "New Jersey . . . to take into account the higher cost of living in New Jersey and to address the distinct needs of the state." (*Id.* ¶¶ 26-27.) CMS approved the amended plan on August 3, 1999. (*Id.* ¶ 26.) The current New Jersey plan includes cost-sharing requirements for Plan C and Plan D enrollees, such as premiums and co-payments. (*Id.* ¶¶ 35-38.) However, "[f]or any family subject to cost-sharing, an annual limit equal to five percent of family income applies, above which no additional cost-sharing is required." (*Id.* ¶ 38.)

Among the crowd-out prevention procedures engaged by New Jersey's plan is a requirement that applicants remain uninsured for some period of time before they are eligible for coverage, subject to certain exemptions. (*Id.* ¶¶ 31-34.) Under the terms of New Jersey's first plan, this period was twelve months. (*Id.* ¶ 31.) However, New Jersey sought, and CMS approved, a plan amendment "[s]hortly after plan implementation" to shorten the twelve-month uninsured period to six months because "[New Jersey] estimated that an additional 6,500 children who had been uninsured for more than six – but less than twelve – months could be covered without triggering any crowd-out effect." (*Id.* ¶ 32.) New Jersey shortened its uninsured period again in 2005, this time to three months. Prior to approving the amendment, however, CMS requested information regarding substitution of private coverage, and New Jersey "committed to performing file reviews to monitor the levels of substitution by applicants, and to return the waiting period to six months should monitoring reveal that more than ten percent of

the applicants were voluntarily dropping coverage." (*Id*. ¶ 33.)

D. August 17, 2007 Letter

On August 17, 2007, Dennis Smith, Director of CMS, sent a letter to state health officials (the "August 17 Letter") concerning crowd-out procedures for state plans that authorized SCHIP eligibility for children whose gross family income exceeded 250 percent of the FPL. (Compl. Ex. A.) The letter purported to "clarify" CMS' understanding of "existing statutory and regulatory requirements" as they applied to such plans, and identified five specific crowd-out procedures previously used in state plans that "should" constitute some portion of the plan's "reasonable procedures" to prevent crowd-out. (*Id*.) The letter goes further and noted that,

> [W]e will expect that, for States that expand eligibility above an effective level of 250 percent of the FPL, the specific crowd-out strategies identified in the State child health plan to include all five of the above crowd-out strategies, which incorporate the following components as part of those strategies: [1] The cost sharing requirement under the State plan compared to the cost sharing required by competing private plans must not be more favorable to the public plan by more than one percent of the family income, unless the public plan's cost sharing is set at the five percent family cap; [2] The State must establish a minimum of a one year period of uninsurance for individuals prior to receiving coverage . . . . In addition, . . . we will ask for . . . [3] Assurance that the State has enrolled at least 95 percent of the children in the State below 200 percent of the FPL who are eligible for either SCHIP or Medicaid . . .[and 4] Assurance that the number of children in the target population insured through private employers has not decreased by more than two percentage points over the prior five year period.

(*Id*.) "The 95 percent assurance serves as a precondition for continued expansion above 250 percent of the FPL." (Compl. ¶ 51.) The letter concluded by explaining that CMS planned to apply this review strategy to all SCHIP state plans and "will work with States that currently provide services to children with effective family incomes over 250 percent of the FPL," and,

finally, that CMS expected states to amend their plans accordingly within twelve months "or CMS may pursue corrective action." (Compl. Ex. A.)

Communications between the parties continued during the interim twelve months. CMS issued a second letter regarding crowd-out procedures on January 25, 2008, this time addressed only to states whose plans afforded eligibility to children with effective family incomes greater than 250 percent of the FPL, like New Jersey. (Kohler Aff. Ex. B.) The January 25 Letter "reaffirm[ed] that [the August 17 Letter's] guidance was specifically designed to apply to new applicants, rather than to individuals currently served by the program." (*Id.*) Additionally, CMS expressed its expectation of "work[ing] cooperatively" with states to bring nonconforming plans into compliance with the "policy guidance" offered by the August 17 Letter, but stated that the states had twelve months, or until August 16, 2008, "to come into compliance with the required crowd-out strategies and assurances" laid out therein. (*Id.*)

In a February 2008 email from CMS' Director of SCHIP Programs, Kathleen Farrell, to the Deputy Commissioner of New Jersey's Department of Health and Human Services, Anne Kohler, DHHS informed New Jersey that CMS would "review any proposed exceptions and justifications [from New Jersey] in making a determination" regarding exceptions to the one-year uninsured guideline. (Kohler Aff. Ex. D.) In a May 7, 2008 letter to state health officials, CMS again reiterated that the strategies identified in the August 17 Letter were to be applied prospectively only, and "need not be applied to prior enrollees" who "can be grandfathered into the State's current coverage and cost sharing levels." (Def. Reply Ex. 1.) This letter also noted that due to the substantial variety of the state plans, CMS would "continue to work with affected States and review requests for alternative approaches on a case-by-case basis." (*Id.*) A few days

later, on May 9, 2008, CMS approved an alternative crowd-out procedure presented by Rhode Island to be used in place of a one-year uninsured period. (Def. Reply. Ex. 2.) Further, CMS found that Rhode Island had provided adequate assurances that it was meeting the 95% enrollment goal. (*Id.*)

E. Effect of the August 17 Letter

To date, New Jersey has not implemented any of the strategies endorsed by the August 17 Letter, yet no enforcement actions against New Jersey have been initiated or threatened by CMS, even after the expiration of the August 16, 2008 "deadline." New Jersey alleges that the "specific, rigid benchmarks" described in the August 17 Letter are different from procedures New Jersey has previously employed with CMS' approval, lack any rational basis, and "contravene the clear intention of the SCHIP statute, which is to allow states flexibility in determining the appropriate and reasonable procedures for their own state plans." (Compl. *passim*.)

New Jersey had not previously implemented any procedures to assure the plan has enrolled ninety-five percent of the state's low-income children, i.e. those whose families earn less than 200 percent of the FPL, and posits that to do so "would have the practical effect of forcing New Jersey to cease the operation of its NJ FamilyCare Plan D as it would be impossible for New Jersey to make this assurance." (*Id*. ¶ 56.) New Jersey argues that it is similarly "impossible" to provide assurances that the state plan is not more favorable than any competing private plan by more than one percent of family income when compared to the cost of private coverage in the group market or set at the five percent family cap. (*Id*. ¶ 67.) In addition to deviating from CMS' historical practice, according to New Jersey, the August 17 Letter's

benchmark of a one year uninsured period "would cause significant hardship as children in families where no insurance was available or affordable would be forced to wait up to a year for coverage." (*Id*. ¶ 48.)

New Jersey further contends that implementation of the "policy guidance" contained within the August 17 Letter "would be costly and time consuming" and would require the state "to amend one regulation and likely promulgate others . . . [which would require] a lengthy and involved process," as well as other time-consuming measures. (Kohler Aff. ¶ 35.)

F. Procedural Background

New Jersey filed this action on October 1, 2007 to enjoin CMS from applying the dictates of the August 17 Letter to its SCHIP plan or from pursuing any corrective action against New Jersey for failing to implement the strategies. In Count I of its Complaint, New Jersey asserts that the "policy guidelines" contained within the August 17 Letter constitute mandatory standards and benchmarks, and are therefore invalid for failure to comply with the APA's rulemaking requirements. In Count II, New Jersey alleges the benchmarks contained in the August 17 letter are without any rational basis and are consequently "arbitrary and capricious," in violation of the APA, 5 U.S.C. § 706(2)(A). Counts III and IV charge CMS with abusing its discretion in imposing the mandatory benchmarks because such imposition was not authorized by, and in fact ran contrary to, the discretion afforded to CMS by the SCHIP statute and its implementing regulations, also in violation of the APA. Finally, Count V alleges that the mandatory benchmarks are themselves contrary to the SCHIP statute and regulations, in violation of the APA.

DHHS filed the instant motion to dismiss under Rule 12 on January 24, 2008, arguing,

inter alia, that this Court is without jurisdiction to entertain the instant dispute because it is not ripe for judicial review. In support of its argument, DHHS submits that the August 17 Letter is not self-executing and will have no concrete effect on New Jersey or any other state unless and until it is applied to them through individualized administrative proceedings. New Jersey opposes the motion, and has been joined by various *amici* in its opposition to dismissal. New Jersey moved for partial summary judgment on its rulemaking claim in March 2008. Oral argument was held before the Court on September 29, 2008.

II. Discussion

Jurisdiction is premised on 28 U.S.C. §§ 1331 and 1346(a)(2). Defendant has moved for dismissal pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction and under 12(b)(6) for failure to state a claim. DHHS argues that the Court is without jurisdiction because: (1) the dispute is not yet ripe, in part because the August 17 Letter does not constitute "final" agency action; (2) there is an "adequate remedy in a court" should New Jersey be adversely affected by a final action by CMS, and the Court is therefore without jurisdiction under the APA; and (3) the SCHIP statute establishes a "mandatory administrative and judicial review scheme" that entrusts jurisdiction over plan conformity disputes to the regional circuit court of appeals, to the exclusion of this Court.

A. Motion to Dismiss for Lack of Subject Matter Jurisdiction

Federal Rule of Civil Procedure 12(b)(1) allows a party to move for dismissal of claims based on a lack of subject matter jurisdiction. Fed. R. Civ. P. 12(b)(1). Where a defendant challenges the jurisdiction on the face of the complaint, the court must assume the veracity of plaintiff's allegations; in contrast, a factual challenge to a court's jurisdiction does not require a

court to afford plaintiff's allegations the presumption of truthfulness. *See Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 891 (3d Cir. 1977); *Dasrath v. Continental Airlines, Inc.*, 228 F. Supp. 2d 531, 534 (D.N.J. 2002); *Med. Soc'y of New Jersey v. Herr*, 191 F. Supp. 2d 574, 578 (D.N.J. 2002) ("A facial attack on jurisdiction is directed to the sufficiency of the pleading as a basis for subject matter jurisdiction," while a factual attack "calls into question the essential facts underlying a claim of subject matter jurisdiction."). In adjudicating a factual 12(b)(1) challenge, the court may consider affidavits, depositions, and testimony to resolve factual issues, and weigh the evidence to satisfy itself as to the existence of its power to hear the case. *Iwanowa v. Ford Motor Co.*, 67 F. Supp. 2d 424, 438 (D.N.J. 1999). Because DHHS' 12(b)(1) motion is a factual challenge to jurisdiction over the instant controversy, the Court does not limit its recitation of the facts to only those alleged in the Complaint. *See, e.g., Med. Soc'y of New Jersey*, 191 F. Supp. 2d at 578-80 (after discussing factual and facial jurisdictional challenges under 12(b)(1), holding certain claims were not ripe for judicial review after considering evidence outside the pleadings).

B. Ripeness

Here, defendant DHHS argues that the Court lacks subject matter jurisdiction over New Jersey's action because it does not invoke an actual case or controversy. DHHS argues primarily that the August 17 Letter does not constitute DHHS' final, definitive position on the issue of crowd-out procedures in state SCHIP plans, and, because plan approval is trusted to the discretion of the CMS Administrator, the August 17 Letter will not have any binding effect unless and until it is applied to individual state plans. DHHS's motion, thus, calls into question whether Article III justiciability exists over this dispute.

The federal courts have limited subject matter jurisdiction and possess "only the power that is authorized by Article III of the Constitution and the statutes enacted by Congress pursuant thereto." *Bender v. Williamsport Area School Dist.*, 475 U.S. 534, 541 (1986). Thus, the justiciability doctrine of ripeness "is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *Reno v. Catholic Social Servs.*, 509 U.S. 43, 57 n.18 (1993). Because a live "case and controversy is a prerequisite to all federal actions," a cause of action must fulfill the ripeness doctrine, which "determines when a proper party may bring an action." *Philadelphia Fed'n of Teachers v. Ridge*, 150 F.3d 319, 322-23 (3d Cir. 1998) (internal quotations omitted). The ripeness doctrine "prevent[s] federal courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also . . . protect[s] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Wyatt, Virgin Islands, Inc. v. Virgin Islands*, 385 F.3d 801, 806 (3d Cir. 2004) (internal quotations omitted). The doctrine "serves to determine whether a party has brought an action prematurely and counsels abstention until such time as a dispute is sufficiently concrete to satisfy the constitutional and prudential requirements of the doctrine." *County Concrete Corp. v. Town of Roxbury*, 442 F.3d 159, 164 (3d Cir. 2006) (internal quotations and citations omitted). A presumption arises that "federal courts lack jurisdiction unless the contrary appears affirmatively from the record[, and i]t is the plaintiffs' responsibility to clearly allege facts that invoke the court's jurisdiction." *Id.* (internal quotations omitted). Further, courts must be aware that though pre-enforcement review of an agency action is available, "[it] is the exception rather than the rule." *Artway v. Attorney General of the State of*

New Jersey, 81 F.3d 1235, 1247 (3d Cir. 1996).

In the seminal case of *Abbott Laboratories v. Gardener*, the Supreme Court directed courts to consider two factors in making ripeness determinations: "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." 387 U.S. 136, 149 (1967), *overruled on other grounds* in *Califano v. Sanders*, 430 U.S. 99, 105 (1977). Within the context of the APA, the hardship inquiry assesses whether the impact of the administrative action would be felt immediately by those subject to it, while the fitness inquiry takes stock of the legal issues of the case, assessing whether further factual development, by way of an expanded administrative record, would improve the court's ability to adjudicate the issues. Indicia of both factors is essential for a finding of ripeness. *But see DRG Funding Corp. v. Sec'y of Housing & Urban Development*, 76 F.3d 1212, 1215 (D.C. Cir. 1996) (noting that "claims of hardship will rarely overcome the finality and fitness problems inherent in attempts to review tentative [administrative agency] decisions"). The Court addresses both elements in turn for each of New Jersey's claims that: (1) the issuance of the August 17 Letter violated the APA's rulemaking requirements by not having a notice and comment period (the "rulemaking claim"); (2) the August 17 Letter's guidelines lack a rational basis and are therefore arbitrary and capricious under the APA; and (3) the guidelines are an abuse of CMS' discretion and contrary to the SCHIP statute and implementing regulations.[1]

1. Hardship to New Jersey of Withholding Judicial Review

The hardship factor in a court's ripeness review examines whether the "impact of the

[1] The claims in groups (2) and (3) will be referred to collectively as the "non-rulemaking claims."

administrative action could be said to be felt immediately by those subject to it in conducting their day-to-day affairs." *Toilet Goods Ass'n, Inc. v. Gardner*, 387 U.S. 158, 164 (1967). New Jersey argues that its failure to come into compliance with the terms of the August 17 Letter might result in the hardship of New Jersey's being subjected to a number of adverse actions, including DHHS' withholding all SCHIP funding or imposition of costly sanctions. Further, New Jersey suggests it would be forced "to revise its entire state plan, to promulgate new regulations, and potentially to adopt costly measures that would enable the state to provide the assurances demanded by the letter", which could entail, for example, New Jersey "chang[ing] its waiting period through a regulatory revision . . . requir[ing] notice and a hearing . . . [and] review by the Legislature," or New Jersey initiating audits of private employer-provided health insurance plans. (Pl. Br. 20-21.) In sum, New Jersey claims that it "confronts an untenable dilemma: [e]ither the State will face the possibility of corrective action and the loss of its SCHIP funding or it must conform its plan, at great expense, to the requirements of the [August 17 Letter]." (Pl. Br. 21.)

New Jersey urges this Court to find its "dilemma" to be analogous to the hardship faced by the petitioners in *Abbott Laboratories*. However, the comparison is inapt. In that case, a consortium of drug manufacturers challenged regulations promulgated by the Commissioner of the Food and Drug Administration, pursuant to a 1962 Congressional amendment to the Federal Food, Drug, and Cosmetic Act which required manufacturers of prescription drugs to "prominently" display the drug's established, as opposed to propriety, name on its packaging. *See* 387 U.S. 136 (1967). The challenged regulations established specific labeling and advertising requirements, including a requirement that the drug's established name be used each

time the drug's proprietary name appears, and were effective immediately upon publication. *See id.* at 138. The Supreme Court held that the pre-enforcement challenge was ripe for judicial review because (1) both sides had conceded that the issue was legal in character and no claims were made that additional administrative proceedings were contemplated, *id.* at 149, (2) the challenged regulation was a "final" administrative action as demonstrated by its formal publication, *id.* at 151-52; and (3) the regulated parties faced the immediate and significant hardship of either modifying all of their labels and promotional materials to include the established prescription drug name to comply with the self-executing regulations, or else "risk serious criminal and civil penalties for the unlawful distribution of 'misbranded' drugs." *Id.* at 152-53 (noting that the regulation "require[d] an immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance"). The regulated parties in *Abbott Laboratories* faced incurring penalties immediately based on its *present* conduct. Despite its arguments to the contrary, New Jersey finds itself in no such dilemma.

In contrast, New Jersey's "dilemma" of choice is not nearly so certain. For example, if New Jersey chooses to ignore the August 17 Letter's guidance, but engages in plan discussions with CMS, there are two possible results: either the two parties reach agreement on New Jersey's SCHIP plan as they have in the past for each of New Jersey's submitted SCHIP plans, or the parties fail to find common ground. In the latter instance, CMS could next initiate an enforcement action against New Jersey, which would afford New Jersey a reasonable opportunity for correction and a formal hearing on the August 17 Letter's guidance. Financial sanctions could be imposed only after this hearing resulted in the CMS Administrator's finding the plan to

be "in substantial noncompliance" with the SCHIP statute. *See* 42 U.S.C. § 1397ff(c), (d); 42 C.F.R. §§ 457.203, 457.204. Even then, New Jersey could avail itself of the judicial procedures outlined in the SCHIP statute. *See* 42 C.F.R. § 457.208 ("Any State dissatisfied with the Administrator's final determination on approvability of plan material (§ 457.203) or compliance with Federal requirements (§ 457.204) has a right to judicial review" in "the U.S. Court of Appeals for the circuit in which the State is located."). Therefore, even if the CMS Administrator finds New Jersey's plan to be noncompliant, it is "a determination that can then be promptly challenged through an administrative procedure, which in turn is reviewable by a court. Such review will provide an adequate forum for testing the [application of the August 17 letter] in a concrete situation." *Toilet Goods Ass'n, Inc.*, 387 U.S. at 165. Although New Jersey risks losing access to the matching federal funds during the pendency of an appeal, such hardship is speculative at best and not of the direct and immediate character as that faced in *Abbott Laboratories*. Further, any corrective action taken on the basis of the August 17 Letter would be applied only prospectively. Each of these circumstances distinguishes New Jersey's present position from the untenable dilemma confronting the regulated parties in *Abbott Laboratories*. That New Jersey must now face the administrative inconvenience of engaging in continued plan negotiations with CMS, and might face enforcement actions at some unidentified point in the future does not rise to the requisite level of hardship warranting judicial intervention at this time.

2. Fitness for Judicial Review

To assess the fitness of a challenge to an administrative agency's action, a court must consider "whether the issues presented are purely legal, whether the agency action is final for purposes of section 10 of the [APA], and whether further factual development would

significantly advance [the reviewing Court's] ability to deal with the legal issues presented." *Univ. of Med. & Dentistry of New Jersey*, 347 F.3d 57, 68 (3d Cir. 2003) (internal citations and quotations omitted). Even assuming New Jersey is correct that its claims are all "purely legal," (Pl. Br. 23), it is clear that further factual development of the administrative record would significantly advance the Court's ability to consider New Jersey's claims and that the August 17 Letter does not constitute "final" agency action.

"The more that the question presented is purely one of law, and the less that additional facts will aid the court in its inquiry, the more likely the issue is to be ripe, and vice versa." *Artway,* 81 F.3d at 1249. The Court agrees that New Jersey's rulemaking claim is predominantly legal; however, the claim is also not ripe for judicial review because essential to the determination of whether the August 17 Letter constitutes a legislative rule requiring notice and comment is discerning the intended legal effect of the rule adopted. Unlike interpretive rules, legislative rules impose new duties upon the regulated parties and have the force and effect of law. *See SBC Inc. v. Fed. Commc'ns Comm'n*, 414 F.3d 486, 498-99 (3d Cir. 2005) (noting that, in contrast, "[a]n interpretive rule simply states what the administrative agency thinks the statute means, and only reminds parties of existing duties") (internal quotes omitted). Courts can evaluate "several factors, including the text of the rule and the procedure the agency had used to promulgate it, in deciding whether it was 'interpretive' or 'legislative' in nature. The rule's classification as 'interpretive' [is] an important but not dispositive factor." *Matter of Seidman*, 37 F.3d 911, 931 (3d Cir. 1995). With no concrete application of the August 17 Letter's guidelines to individual state SCHIP plans to consider, the Court is satisfied that the interests of judicial economy are better served by postponing judicial review until a more robust factual

record exists to provide insight as to the effect of the August 17 Letter when applied to individual states such as New Jersey. Further, as previously addressed, the Court finds no indicia of hardship due to the withholding of judicial review. Therefore, the Court is persuaded that postponement of review of the rulemaking claim will avoid engaging in "piecemeal review which at the least is inefficient and upon completion of the agency process might prove to have been unnecessary." *F.T.C. v. Standard Oil Co. of California*, 449 U.S. 232, 242 (1980).

As to the non-rulemaking claims, DHHS argues that New Jersey's claims require additional fact development because there is no administrative record by which to evaluate the reasonableness of the August 17 Letter. (Def. Br. 16.) New Jersey argues that the only indispensable facts can be taken from the historical administrative record, and that there are no additional facts necessary to consider, for example, whether the benchmarks from the August 17 Letter are arbitrary and capricious. (Pl. Br. 25.) However, where the focus of New Jersey's challenge is that certain of the crowd-out procedures in the August 17 Letter are impossible or unduly burdensome to incorporate into its state plan, a full administrative record detailing CMS' justifications for its endorsement of these particular crowd-out procedures, as well as New Jersey's empirical challenges to those justifications, is necessary to assess whether the crowd-out measures in the August 17 Letter are arbitrary and capricious or contrary to the SCHIP statute and regulations, and whether CMS abused its discretion in connection with the August 17 Letter. In the absence of a concrete administrative record "in which competing associational and governmental interests can be weighed, [this Court] is simply not in a position to determine" whether the crowd-out procedures from the August 17 Letter are arbitrary and capricious, contrary to the SCHIP statute and regulations, or an abuse of CMS' discretion. *California*

Bankers Ass'n v. Shultz, 416 U.S. 21, 56 (1974).

The administrative record is inadequate in part because there is no final agency action being reviewed. *See CEC Energy Co., Inc. v. Public Serv. Comm'n of Virgin Islands*, 891 F.2d 1107, 1110 (3d Cir. 1989) (identifying "whether the [agency] decision involves a pure question of law that does not require further factual development" as one of seven factors to assess finality of an agency action). Ripeness and finality are closely related, and the APA limits non-statutory judicial review to "final" agency actions. *See* 5 U.S.C. § 704; *Univ. of Med. & Dentistry of New Jersey*, 347 F.3d at 68 ("And as we have noted, the Court's treatment of the finality issue has involved an inquiry into the broader question of whether a given action is ripe for judicial review.") (internal quotations omitted). Critical to the finality inquiry is "whether the decision represents the agency's definitive position on the question" and "whether the decision has the status of law with the expectation of immediate compliance." *Univ. of Med. & Dentistry of New Jersey*, 347 F.3d at 69. When applied to the instant case, where both parties contemplate further negotiations regarding New Jersey's SCHIP plan, the answer to both questions must be "no."

It is clear that the guidance contained in the August 17 Letter will be considered in evaluating any plans submitted by New Jersey in the future. However, what effect that consideration will have on CMS' ultimate decision whether to approve that plan is unknown. New Jersey and CMS could reach agreement on crowd-out measures to include in New Jersey's plan, or New Jersey might disengage from the negotiation process. As the plan review process affords discretion to CMS in approving state plans, how CMS will exercise that discretion in light of the August 17 Letter is unknown. In fact, CMS approved Rhode Island's SCHIP plan notwithstanding its omission of a one year uninsured waiting period, because Rhode Island was

able to offer an acceptable alternative crowd-out measure. (Reply Br. Ex. 2.) Therefore, the August 17 Letter cannot be understood to constitute the agency's "definitive position on the question" or as a decision with the status of law, as CMS has approved plans that are not in strict compliance with the measures identified in it.

However, even if New Jersey were to refuse to integrate any of the August 17 Letter's measures, it is uncertain whether CMS would commence enforcement procedures. *See Univ. of Med. & Dentistry of New Jersey*, 347 F.3d at 69 ("Here, as in most actions, the possibility that no enforcement action may be taken is real for several reasons, not least of which is that the [administrative officer] may change her mind on one or more issues along the way. 'Judicial intervention into the agency process denies the agency an opportunity to correct its own mistakes.'") (quoting *F.T.C. v. Standard Oil*, 449 U.S. at 242). It is this uncertainty that renders New Jersey's claims unfit for judicial review, because New Jersey in effect "ask[s] the court to declare . . . deficient procedures that have yet to be applied." *Philadelphia Fed'n of Teachers*, 150 F.3d at 324 (finding a procedural due process challenge to an amendment to the Pennsylvania workers' compensation statute unripe for review where though it was clear that the amendment would be applied to union member-plaintiffs, because it was unclear how the amendment would operate against plaintiffs, the court held the claim was unfit for judicial review and "[s]uch a [declaratory] judgment would be premature").

Unlike in *Abbott Laboratories,* further administrative action with regards to New Jersey's SCHIP plan is clearly contemplated, as the SCHIP plan approval process contemplates on-going discussions with states. The only certain effect New Jersey faces as a result of the August 17 Letter is an expectation that the state will engage in further discussions and negotiations with

CMS to establish a SCHIP plan both parties can agree on. As previously stated, the result of these discussions, and the degree and character of CMS' reliance on the August 17 Letter, is presently unknown. *See Univ. Med. & Dentistry of New Jersey*, 347 F.3d at 71 (holding a suit was unripe, where the agency's decision to use a certain standard in determining whether an audit should be commenced constituted the challenged "agency action" and could not be final agency action where "[t]he only apparent effect from that choice would come if and when it resulted in a conclusion about plaintiffs' compliance with the applicable standards. . . we are not now in a position to assess what might or might not happen at the end of this process."). Therefore, this Court holds that there is no sufficiently "final" action by DHHS (or CMS) for New Jersey to challenge.

III. Conclusion

In conclusion, New Jersey "merely fear[s] potential future administrative . . . action and . . . the dispute between the parties is contingent upon events that may not occur at all or may occur differently than anticipated." *Wyatt*, 385 F.3d at 808. Review at this juncture threatens the type of abstract disagreement over administrative policies that the ripeness doctrine is intended to avoid. New Jersey suffers no serious hardship by postponing judicial review at this time, as it will have adequate opportunities to challenge the August 17 Letter's guidance through the discussions with CMS and, if necessary, through an administrative hearing with an appeal to the Third Circuit. Until New Jersey faces enforcement actions based on the CMS Administrator finding its plan to be substantially noncompliant or some other concrete adverse impact, this Court holds that the instant controversy is not ripe for resolution by the federal courts, and is, accordingly, dismissed. An appropriate Order accompanies this Opinion.

Dated: November 17, 2008